UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/544,150	08/01/2005	Francis X. Smith	3009040 US01	6441

44331 7590 05/28/2009

HISCOCK & BARCLAY, LLP
2000 HSBC PLAZA
100 Chestnut Street
ROCHESTER, NY 14604-2404

EXAMINER	
BASQUILL, SEAN M	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
05/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/544,150	SMITH, FRANCIS X.	
	Examiner	Art Unit	
	Sean Basquill	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9, 11-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *29 Jan 2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants are advised, in future correspondence with the office, to reflect the change of examiners from TRISTAN MAHYERA to SEAN BASQUILL.

Status of the Claims

1. Applicant's amendments, filed 25 March 2009, have been entered. Claims 1 and 9 have been amended, and Claim 10 cancelled. New Claims 12-14 have been entered, leaving Claims 1-9 and 11-14 presented for examination.

Previous Rejections

2. Applicants' arguments, filed 25 March 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 9, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 2,445,366 (hereinafter "Rigby").

As a threshold matter, the examiner has interpreted the phrases "contact lens" of Claim 1 and "Ophthalmic" of Claims 9 and 12 as reciting intended uses of the solutions. These phrases are therefore afforded no significance in the construction of the claims as presented.

Rigby discloses specific examples of ophthalmic solutions containing 0.028% thiamine hydrochloride, 0.028% ascorbic acid as an antioxidant, and 2% boric acid.[1]

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-4, 7-9, and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,817,277 ("Mowrey-McKee") in view of British Patent Specification Publication GB 1,431,841 (hereinafter "Evans").

Mowrey-McKee discloses the contact lens disinfecting solutions and methods as put forth in the previous action, but does not specify that compounds such as thiamine, riboflavin, niacin, dexpanthenol, or pantothenic acid may be included.

Evans describes an ophthalmic nutritional preparation for promoting the health of the eye and treatment of ophthalmic disorders. (Pg.1, L.9-25). These preparations contain a variety of vitamins, including thiamine, riboflavin, niacin, and pantothenic acid in a suitable form, including eye lotions or eye drops. (Pg.2, L.31-60). These compounds are to be included in amounts ranging from 0.5-20 milligrams. (Pg. 2, L. 40-60). Evans additionally indicates that

[1] John A Moore, *et al*, *An Assessment of Boric Acid and Borax using the IEHR Evaluative Process for Assessing Human Developmental and Reproductive Toxicity of Agents*, 11 REPRODUCTIVE TOXICOL. 123, 128 (1997) (indicating boric acid is commonly used as a preservative in pharmaceutical applications).

ocular disorders may be treated by using "a multiple of the formula...which may be combined with additional quantities of additional nutrients." (Pg.2, L.1-3).

It would have been prima facie obvious to one having ordinary skill in the art at the time of the instant invention to have incorporated the nutritional preparation of Evans into the ophthalmic solution of Mowrey-McKee. One having ordinary skill in the art at the time of the instant invention would have been motivated to do so because both Mowrey-McKee and Evans describe solutions useful for treating ophthalmic conditions, and generally it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose, namely a composition for the treatment of ocular disorders. The idea for combining them flows logically from their having been individually taught in the prior art. MPEP 2144.06.

Furthermore, given the general conditions of B-vitamin content described by Evans and Mowrey-McKee, it would have been obvious for a skilled artisan to arrive at the instantly claimed B-vitamin concentrations by the optimization of concentrations through routine experimentation. One having ordinary skill in the art would have been motivated to experiment with the B vitamin concentrations described by Evans and Mowrey-McKee because Evans specifically indicates that the quantities of vitamins, including the B vitamins therein described, included for the treatment of ocular disorders may be adjusted according to the disorder being treated. Vitamin concentration is therefore recognized by the prior art as a result-effective variable, wherein the result being achieved is the effective treatment of a variety of ocular disorders.

5. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mowrey-McKee as modified by Evans as applied to claims 1-4, 7-9, and 11-14 above, and further in view of U.S. Patent 6,162,393.

Mowrey-McKee as modified by Evans describes an ophthalmic composition comprising thiamine, riboflavin, niacin, and pantothenic acid as well as PHMB, preservatives, sequestering agents, and buffers, but does no specify the use of glycerin or decanedioic acid.

De Bruiji discloses the use of glycerin and decanedioic acid in ophthalmic compositions as described in the previous action.

It would have been prima facie obvious to one having ordinary skill in the art at the time of the instant invention to have combined the glycerin or decanedioic acid of De Bruiji with the topical ophthalmic composition of Mowrey-McKee as modified by Evans. One having ordinary skill in the art would have been motivated to do so because glycerin or decanedioic acid because glycerin can reduce any minor toxic effects imparted to mammalian cells by a disinfectant and decanedioic acid increases the ocular comfort of contact lens solutions.

Double Patenting

6. Claim 10 stands provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 11 of copending Application No. 11/620,318. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

This rejection is maintained since applicant has (effectively) not responded to the rejection in a substantive manner. See 37 CFR § 1.111(b) and MPEP § 714.02.

7. Claims 1-9 and 11 stand and Claims 12-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 11/620,318. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons put forth in the previous action. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

This rejection is maintained since applicant has (effectively) not responded to the rejection in a substantive manner. See 37 CFR § 1.111(b) and MPEP § 714.02.

Conclusion

No Claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean Basquill
Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612